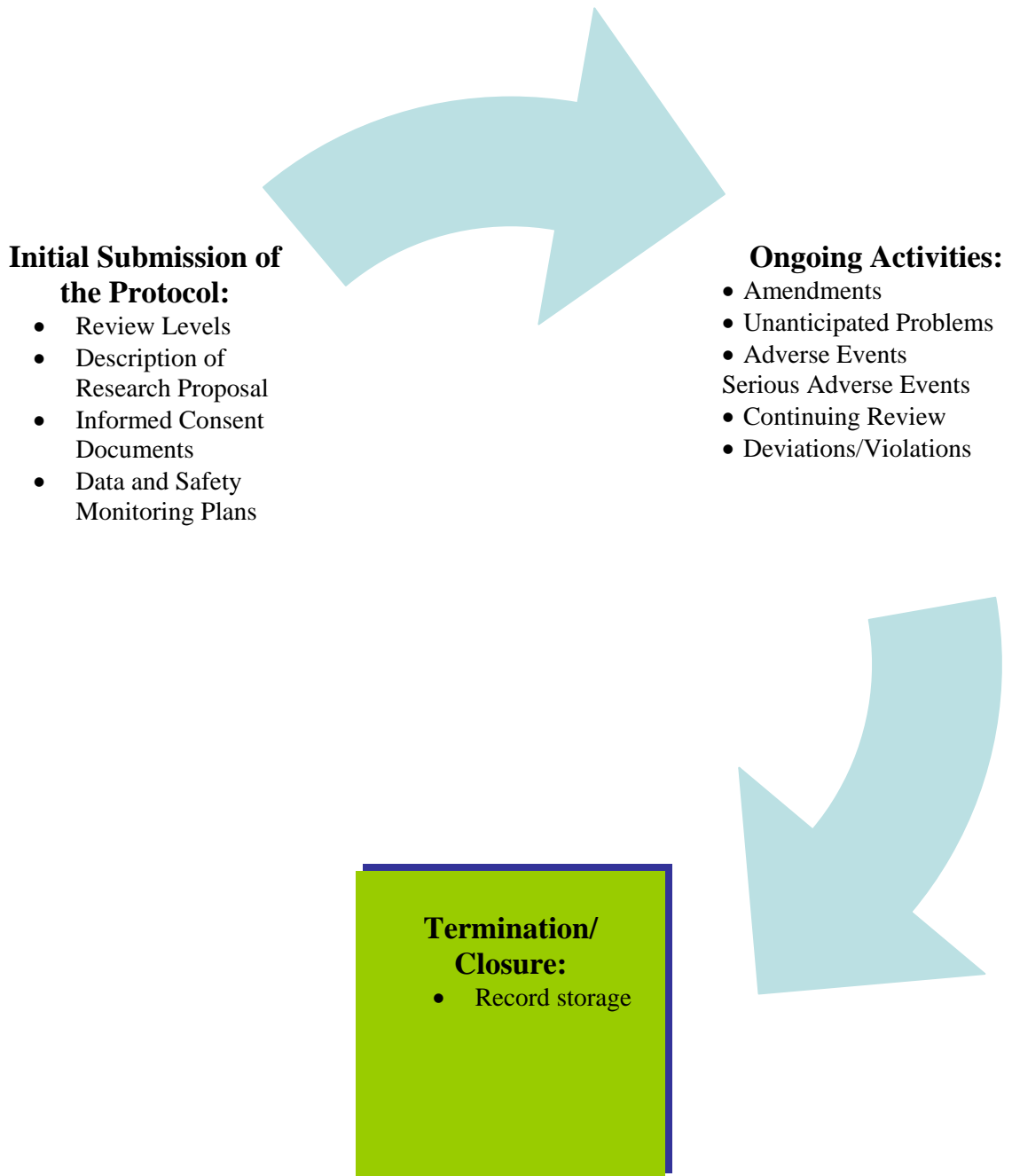


HAC Policies and Procedures

What Are the Activities Associated with Terminating/Closing a Protocol?

The typical protocol is terminated at the completion of the protocol and data analysis. These requests for terminations must be submitted to the HAC by the PI. Sometimes, the HAC will terminate the approval of a protocol or the PI may fail to request continuing review. More information about terminating/closing a protocol is included in this section.



HAC Policies and Procedures

Closing/Terminating a Protocol

HAC Policies and Procedures

Closing/Terminating A Protocol

I Have Completed My Study – Can I Close The HAC Approval?

A study may not be terminated if research subjects are in follow-up or if data are still being analyzed. However, if all research subjects have completed study participation and all data has been analyzed, the study may be closed.

Can I Just Call Or Email To Terminate My Study?

No. A phone call or e-mail message is inadequate to terminate a study. An [HAC Form 111](#), Final Study Report, must be utilized to terminate the study. The [HAC Form 107](#), Clinical Study Status Report, may be used if the termination coincides with the approval expiration date.

Who Is Responsible For Notifying Other Departments Such As MCGHI Patient Accounting, Division Of Sponsored Programs Administration, Augusta Veterans Affairs Medical Center, Etc. the Study is Terminated?

The PI is responsible for notifying all other departments.

I Am Leaving MCG/MCGHI/Augusta VAMC. Do I Close My Protocol Here?

Yes.

The PI Left MCG/MCGHI/Augusta VAMC Without Naming A New PI. What Do We Do?

The department chairperson assumes responsibility for naming a new principal investigator. If a new PI is named, submit a completed HAC Form 113 to the HAC Administrative Office. Other forms and documentation such as a revised informed consent document may be required. If the protocol is externally sponsored, confirm the sponsor's approval of the new PI prior to submitting HAC paperwork. Notify DSPA and/or ABRC as appropriate. Contact the HAC Administrative Office for additional assistance.

What HAC Form Do I Complete To Terminate The Study?

An [HAC Form 111](#), Final Study Report, must be utilized. The [HAC Form 107](#), Clinical Study Status Report, may be used if the termination coincides with the approval expiration date.

What Information Should Be Included In The Final Report?

At study termination or completion, a timely final report must be submitted to the Human Assurance Committee (HAC). It must include the number of enrolled, discontinued and completed subjects, and the number of signed informed consent forms in the investigator's files for the entire project. Please be as informative as possible.

Sample Guidance Statement for the summarization report section:

HAC Policies and Procedures

"Twelve medical records were reviewed. The data were gathered and protected per the Description of Research Proposal. The poster presentation was made at the July meeting of National Principal Investigators. The study is now complete."

What Other Documents Are Required If The Study Is Industry Sponsored?

A copy of the sponsor termination letter should accompany the [HAC Form 111](#), Final Report, or HAC Form 107, Clinical Study Status Report, if utilized when the termination occurs during the approved project period.

Who Do I Contact if I Have Any Questions?

Contact the HAC Administrative Office at HAC@mcg.edu or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.

HAC Policies and Procedures

Record Storage

HAC Policies and Procedures

Why Do I Have To Keep The Information?

You are required to keep the information for several reasons including federal regulations, state law, Board of Regents' policies, institutional policies and good clinical practice.

What Do I Do With All The Documents And Records?

If your department has storage space you can store them on site. You may also arrange for long-term storage off site.

What Do I Do If I Need Access To A Terminated HAC File?

Each request must go through the OHRP staff to gain access to those records.

How Long Do Study Records Need To Be Stored Following Study Closure? Our Study Has Been Over For About Three Years. How Long Do We Have To Store This Stuff?

Per FDA 21 CFR312.62 Investigator record keeping and record retention:

- a. Disposition of drug. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 312.59.
- b. Case histories. An investigator is required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the investigational drug or employed as a control in the investigation.
- c. Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

Per ICH Guidelines 4.9 Records and Reports, Section 4.9.5:

Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing application in an ICH region at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see section 5.5.12).

HAC Policies and Procedures

For studies that are conducted at the Augusta VAMC, please refer to the VA section.

Can We Ask The Sponsor to Provide for Long-Term Storage?

Absolutely! Contact the sponsor and ask if they can store the documents after the two-year obligation is met. Some will store the information or they will provide written documentation to destroy the records.

Is There A Current Institution SOP For Research Record Storage?

The institution currently has no policy on record retention, other than the FDA regulation. The institution is in the process of preparing a SOP for this. As far as budgetary information, this is an investigator decision.

The CFR regulations only apply to those studies under FDA jurisdiction.

HAC Policies and Procedures

HAC Record Storage

How Does The HAC Limit Access To Their Records?

The HAC limits access to HAC files to the OHRP staff, HAC members, research team members and others who submit a request in writing to the HAC and the Principal Investigator.

How Does The HAC Store All Active Research Protocols?

All active research protocols are maintained in a keypad protected room while being stored and then in individual locked offices while in use. In/Out records are used as well as a file log in the HAC office of the OHRP suite.

How Does The HAC Store Terminated Research Protocols?

All terminated files (within the past year) are maintained in a locked storage space in the OHRP suite and as space permits. All terminated files (with expiration dates greater than one year ago) are maintained at a local secure data storage facility with limited access.

How Long Does The HAC Maintain These Records?

The HAC has a letter of agreement with the FDA that records will be maintained for 25 years.

FDA 21 CFR 56.115 b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

HHS regulations at 45 CFR 46.115(b) require that IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner.